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*Yao*

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,736	01/06/2004	Robert Vincent Martinez	31896-002000	2977

22204 7590 05/23/2005

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EXAMINER
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YAO, LEI

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/751,736

Applicant(s)

MARTINEZ ET AL.

Examiner

Lei Yao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claims 1-20 are drawn to methods using multiple compounds or compounds that fail Harnish est. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group share a substantial structural feature disclosed as being essential to that utility.

#### Invention Groups 1-59:

Claims 1-8, drawn to a method for detecting a level of a polypeptide encoded by colon cancer gene and comparing the expression profile of colon cancer gene, which is selected from SEQ ID NO: 68-126, classified in class 435, subclass 4.

#### Invention Groups 60-118:

Claim 9, drawn to a method for detecting a level of T cells that are activated by one polypeptide encoded by colon cancer gene selected from SEQ ID NO: 68-126, classified in class 435, subclass 325.

#### Invention Groups 119-177:

Claims 10-11, drawn to a pharmaceutical composition comprising a polypeptide encoded by colon cancer gene selected from SEQ ID NO: 68-126, classified in class 530, subclass 300, 350.

#### Invention Groups 178-236:

Claims 10-11, drawn to a pharmaceutical composition comprising a polynucleotide of colon cancer gene selected from SEQ ID NO: 5-63, classified in class 536, subclass 23.1.

#### Invention Groups 237-354:

Claim 12, drawn to a method for administering one composition from invention group 119-236, classified in class 514, subclass 2 and 44.

#### Invention Groups 355-472:

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Claims 13-14 and 16, drawn to a pharmaceutical composition to modulating the colon cancer gene or gene product comprising binding agent, activated T cells, DNA, antibody, inhibitor, polynucleotide encoding siRNA or antisense, a colon cancer gene selected from SEQ ID NO: 5-63 or 68-126, classified in class 530, subclass 350 or 387.1, class 536, subclass 23.1, or class 435, subclass 325.

Invention Groups 472-590:

Claim 15, drawn to a method comprising administering a composition of group 355-472, classified in class 424, subclass 130.1 and class 514, subclass 2 or 44.

Invention Groups 534-597:

Claim 17, drawn to diagnostic kit comprising a DNA hybridizing a sequence selected from SEQ ID NO: 1-63, a complement,

Invention Groups 654-717:

Claim 17, drawn to diagnostic kit comprising an antibody of binding to protein from SEQ ID NO: 64-126, classified in class 536, subclass 23.1.

Invention Groups 718-836:

Claim 20, drawn to a method for identifying an agent capable of modulating gene expression in a colon cancer cells, a gene selected from SEQ ID NO: 5-63 or 68-126, unclassified.

Invention Groups 837:

Claim 18, drawn to DNA array, classified in class 536, subclass 23.1.

Invention Groups 838:

Claim 19, drawn to protein array, classified in class 435, subclass 7.1.

Inventions Groups 119-236 and Groups 237-354 are related as product and process of use.

Inventions Groups 355-472 and Groups 472-590 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the

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instant cases the polypeptide or polynucleotide of Groups 119-236 can be used to immunize an animal to produce antibodies or to make proteins, as opposed to being used for administering subjects and the binding agents of Groups 355-472 can be used for detecting cancer in vitro, as opposed to being used for administering subjects.

Inventions 1-59, 60-118, 237-354, 472-590 are 718-838 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to method using different active ingredients that have different functions. Detecting a polypeptide and detecting activation of T-cell operates differently in cell-free or cell systems. Administrations of different materials to different subjects require different patient population, have different method steps and may lead to different effects. DNA and protein microarraies require different materials and have different method steps. Identifying a modulating agent in a cancer cell operates differently from above methods because the method needs testing structural different materials, which potentially regulate a gene expression in a cell. Search of the methods together are not co-extensive in text searching in non-patent literature and US patent database.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

### ***Election of Species***

This application contains claims directed to the following patentably distinct species of the claimed invention:

Group 355-472 contain claims directed to the following patentably distinct species:

- A. one iRNA selected from table 7
- B. one antisense RNA selected from table 7
- C. Antibody

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D. One inhibitor except species A, B, and C.

applicant is required under 35 U.S.C. 121 to elect **a single disclosed species** from A, B, C, or D for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. Failure to do so may result in a

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loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

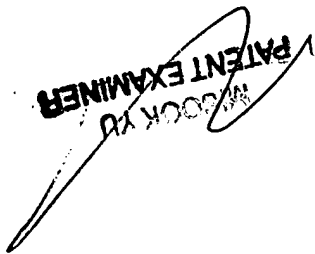
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.  
Examiner  
Art Unit 1642

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